

**REMARKS**

Claims 34 to 43 have been cancelled and new claims 44 to 53 have been added in order to more particularly point out that which applicants regard as their invention.

Specifically, independent claim 34 recited characteristics of the cell-lines and of the pre-selected substance, if an allergen. However, the characteristics of the cell-lines are not needed, as all mast cell-lines and basophil cell-lines have the recited characteristics, and therefore are useful in the present invention. Further, the capability of the pre-selected substance to activate immunoglobulin independent release of cell mediators or, subsequently, immunoglobulin dependent release of cell mediators is irrelevant because one need not know how an invention works in order for it to be patentable. It is sufficient to know that if cell mediators are released, the pre-selected substance is allergenic.

The new claims are supported by the specification, page 6, line 1 to page 7, line 26 and by Example 2, page 15, line 17 to page 17, line 7.

In the prior Office Action, the Examiner rejected the cancelled claims under 35 U.S.C. § 112, first paragraph, for lack of written description. The Examiner asserted that there was no support in the specification for the characterization of the cell-lines and the characterization of the pre-selected substance.

While applicants disagree with the Examiner's view of whether the specification contains a written description of cancelled claim 34, applicants have presented a new independent claim that does not characterize the cell-line or the pre-selected substance. Therefore, this issue is moot.

Further, new claim 44 distinguishes over references that teach that mast or basophil cell-lines release one or more cell mediators upon exposure to a pre-selected substance, because none of those references teaches one of the novel aspects of the present invention, which is that release of cell mediators in the absence of a sensitizing agent correlates with whether a pre-selected substance is an allergen. The present inventors were the first to make this observation and fashion a method based upon the observation. For this reason, *Levi-Schaffer*, previously cited by the Examiner, does not make obvious the present invention.

More specifically, *Levi-Schaffer* is directed to an assay for detecting anti-inflammatories and discloses that mast cell-lines released histamine in response to exposure to some naturally occurring substances in the absence of an immunoglobulin sensitizing agent. *Levi-Schaffer* is concerned with how to prevent a mast cell from being activated and thereby releasing histamine. *Levi-Schaffer* does not teach or suggest that the observed histamine release can be correlated with the ability of a substance to cause an allergic response. *Levi-Schaffer* in no way teaches or suggests to characterize the different “secretagogues” he used to stimulate the mast cells as being or not being potential allergens.

Accordingly, the present claims have written description in the present specification and recite an invention that is not made obvious over or anticipated by observing histamine release from mast cells.

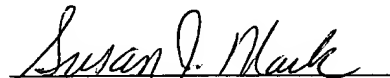
Thus, the Examiner is respectfully requested to pass the case to issuance.

In a telephone conference with the Examiner after issuance of the Advisory Action in the above-identified case, the Examiner stated that he would be amenable to an interview before

Preliminary Amendment  
09/133,766  
Page 5

issuing a first Office Action after the CPA is filed. Accordingly, the Examiner is respectfully requested to hold in abeyance any action on this case until such interview has been conducted.

Respectfully submitted,

A handwritten signature in cursive script, reading "Susan J. Mack", written over a horizontal line.

Susan J. Mack  
Registration No. 30,951

SUGHRUE MION, PLLC  
2100 Pennsylvania Avenue, N.W.  
Washington, D.C. 20037-3213  
Telephone: (202) 293-7060  
Facsimile: (202) 293-7860  
Date: June 7, 2002